

110TH CONGRESS
1ST SESSION

S. 1776

To amend the Federal Food, Drug, and Cosmetic Act to establish a user fee program to ensure food safety, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 12, 2007

Mr. DURBIN (for himself and Mr. BROWN) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a user fee program to ensure food safety, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; FINDINGS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Imported Food Security Act of 2007”.

6 (b) FINDINGS.—Congress finds that—

7 (1) the safety and integrity of the United
8 States food supply is vital to the public health, to

1 public confidence in the food supply, and to the suc-
2 cess of the food sector of the Nation's economy;

3 (2) illnesses and deaths of individuals and com-
4 panion pets caused by contaminated food—

5 (A) have contributed to a loss of public
6 confidence in food safety; and

7 (B) have caused significant economic losses
8 to manufacturers and producers not responsible
9 for contaminated food items;

10 (3) the task of preserving the safety of the food
11 supply of the United States faces tremendous pres-
12 sures with regard to—

13 (A) emerging pathogens and other con-
14 taminants and the ability to detect all forms of
15 contamination; and

16 (B) an increasing volume of imported food,
17 without adequate monitoring and inspection;

18 (4) the United States is increasing the amount
19 of food that it imports such that—

20 (A) from 2003 to the present, the value of
21 food imports has increased from
22 \$45,600,000,000 to \$64,000,000,000; and

23 (B) imported food accounts for 13 percent
24 of the average Americans diet including 31 per-
25 cent of fruits, juices, and nuts, 9.5 percent of

1 red meat and 78.6 percent of fish and shellfish;
 2 and

3 (5) the number of full time equivalent Food and
 4 Drug Administration employees conducting inspec-
 5 tions has decreased from 2003 to 2007.

6 **SEC. 2. USER FEES REGARDING INSPECTIONS OF IM-**
 7 **PORTED FOOD SAFETY.**

8 Chapter VIII of the Federal Food, Drug, and Cos-
 9 metic Act (21 U.S.C. 381 et seq.) is amended by inserting
 10 after section 801 the following:

11 “USER FEES REGARDING FOOD SAFETY

12 “SEC. 801A. (a) IN GENERAL.—

13 “(1) ASSESSMENT.—Beginning in fiscal year
 14 2008, the Secretary shall in accordance with this
 15 section assess and collect fees on food imported into
 16 the United States.

17 “(2) PURPOSE OF FEES.—

18 “(A) IN GENERAL.—The purpose of fees
 19 under paragraph (1) is to defray the costs of
 20 carrying out section 801 with respect to food.
 21 Costs referred to in the preceding sentence in-
 22 clude increases in such costs for an additional
 23 number of full-time equivalent positions in the
 24 Department of Health and Human Services to
 25 be engaged in carrying out such section.

1 “(B) ALLOCATIONS BY SECRETARY.—Of
2 the total fee revenues collected under paragraph
3 (1) for a fiscal year, the Secretary shall reserve
4 and expend amounts in accordance with the fol-
5 lowing:

6 “(i) The Secretary shall reserve not
7 less than 50 percent for carrying out sec-
8 tion 801 with respect to food, other than
9 research under section 801(p). In expend-
10 ing the amount so reserved, the Secretary
11 shall give first priority to inspections con-
12 ducted at ports of entry into the United
13 States and second priority to the imple-
14 mentation of the import certification pro-
15 gram under section 805.

16 “(ii) The Secretary shall reserve not
17 more than 50 percent for carrying out re-
18 search under section 801(p).

19 “(3) AMOUNT OF FEE; COLLECTION.—A fee
20 under paragraph (1) shall be assessed on each line
21 item of food, as defined by the Secretary by regula-
22 tion. The amount of the fee shall be based on the
23 number of line items, and may not exceed \$20 per
24 line item, notwithstanding subsection (b). The liabil-
25 ity for the fee constitutes a personal debt due to the

1 United States, and such liability accrues on the date
2 on which the Secretary approves the food under sec-
3 tion 801(c)(1). The Secretary may coordinate with
4 and seek the cooperation of other agencies of the
5 Federal Government regarding the collection of such
6 fees.

7 “(b) TOTAL FEE REVENUES.—The total fee revenues
8 collected under subsection (a) for a fiscal year shall be
9 the amount appropriated under subsection (f)(3).

10 “(c) ANNUAL FEE ADJUSTMENT.—Not later than 60
11 days after the end of each fiscal year beginning after fiscal
12 year 2008, the Secretary, subject to not exceeding the
13 maximum fee amount specified in subsection (a)(3), shall
14 adjust the amounts that otherwise would under subsection
15 (a) be assessed as fees during the fiscal year in which the
16 adjustment occurs so that the total revenues collected in
17 such fees for such fiscal year equal the amount applicable
18 pursuant to subsection (b) for the fiscal year.

19 “(d) FEE WAIVER OR REDUCTION.—The Secretary
20 shall grant a waiver from or a reduction of a fee assessed
21 under subsection (a) where the Secretary finds that the
22 fee to be paid will exceed the anticipated present and fu-
23 ture costs incurred by the Secretary in carrying out sec-
24 tion 801 with respect to food (which finding may be made
25 by the Secretary using standard costs).

1 “(e) ASSESSMENT OF FEES.—

2 “(1) LIMITATION.—Fees may not be assessed
3 under subsection (a) for a fiscal year beginning after
4 fiscal year 2008 unless the amount appropriated for
5 salaries and expenses of the Food and Drug Admin-
6 istration for such fiscal year is equal to or greater
7 than the amount appropriated for salaries and ex-
8 penses of the Food and Drug Administration for fis-
9 cal year 2008 multiplied by the adjustment factor
10 applicable to the fiscal year involved, except that in
11 making determinations under this paragraph for the
12 fiscal years involved there shall be excluded—

13 “(A) the amounts appropriated under sub-
14 section (f)(3) for the fiscal years involved; and

15 “(B) the amounts appropriated under sec-
16 tion 736(g) for such fiscal years.

17 “(2) AUTHORITY.—If the Secretary does not
18 assess fees under subsection (a) during any portion
19 of a fiscal year because of paragraph (1) and if at
20 a later date in such fiscal year the Secretary may as-
21 sess such fees, the Secretary may assess and collect
22 such fees, without any modification in the rate of
23 the fees, at any time in such fiscal year notwith-
24 standing the provisions of subsection (a)(3) relating
25 to the time at which fees are to be paid.

1 “(f) CREDITING AND AVAILABILITY OF FEES.—

2 “(1) IN GENERAL.—Fees collected for a fiscal
3 year pursuant to subsection (a) shall be credited to
4 the appropriation account for salaries and expenses
5 of the Food and Drug Administration and shall be
6 available in accordance with appropriation Acts until
7 expended without fiscal year limitation. Such sums
8 as may be necessary may be transferred from the
9 Food and Drug Administration salaries and ex-
10 penses appropriation account without fiscal year lim-
11 itation to such appropriation account for salaries
12 and expenses with such fiscal year limitation. The
13 sums transferred shall be available solely for car-
14 rying out section 801 with respect to food, and the
15 sums are subject to allocations under subsection
16 (a)(2)(B).

17 “(2) COLLECTIONS AND APPROPRIATION
18 ACTS.—The fees authorized in subsection (a)—

19 “(A) shall be collected in each fiscal year
20 in accordance with subsections (a)(3) and (b);
21 and

22 “(B) shall only be collected and available
23 for the purpose specified in subsection (a)(2).

24 “(3) AUTHORIZATION OF APPROPRIATIONS; AL-
25 LOCATIONS BY SECRETARY.—Subject to paragraph

1 (4), there is authorized to be appropriated for fees
2 under this section such sums as may be necessary to
3 carry out the purposes of this section for each of the
4 fiscal years 2008 through 2012. Such appropriated
5 funds may be in addition to any other funds appro-
6 priated for such purposes.

7 “(4) OFFSET.—Any amount of fees collected
8 for a fiscal year under subsection (a) that exceeds
9 the amount of fees specified in appropriation Acts
10 for such fiscal year shall be credited to the appro-
11 priation account of the Food and Drug Administra-
12 tion as provided in paragraph (1), and shall be sub-
13 tracted from the amount of fees that would other-
14 wise be authorized to be collected under this section
15 pursuant to appropriation Acts for a subsequent fis-
16 cal year.

17 “(g) COLLECTION OF UNPAID FEES.—In any case
18 where the Secretary does not receive payment of a fee as-
19 sessed under subsection (a) within 30 days after it is due,
20 such fee shall be treated as a claim of the United States
21 Government subject to subchapter II of chapter 37 of title
22 31, United States Code.

23 “(h) CONSTRUCTION.—This section may not be con-
24 strued as requiring that the number of full-time equivalent
25 positions in the Department of Health and Human Serv-

ices, for officers, employees, and advisory committees not engaged in carrying out section 801 with respect to food be reduced to offset the number of officers, employees, and advisory committees so engaged.

“(i) DEFINITION OF ADJUSTMENT FACTOR.—For purposes of this section, the term ‘adjustment factor’ applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April 2007.”.

SEC. 3. RESEARCH ON TESTING TECHNIQUES FOR FOOD SAFETY INSPECTIONS OF IMPORTED FOOD; PRIORITY REGARDING DETECTION OF INTENTIONAL ADULTERATION.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

“(p) RESEARCH ON TESTING TECHNIQUES FOR FOOD SAFETY INSPECTIONS OF IMPORTED FOOD.—

“(1) IN GENERAL.—The Secretary shall (directly or through grants or contracts) provide for research on the development of tests and sampling methodologies, for use in inspections of food under this section—

1 “(A) whose purpose is to determine wheth-
2 er food is adulterated by reason of being con-
3 taminated with microorganisms or pesticide
4 chemicals or related residues; and

5 “(B) whose results are available not later
6 than approximately 60 minutes after the ad-
7 ministration of the tests.

8 “(2) PRIORITY.—In providing for research
9 under paragraph (1), the Secretary shall give pri-
10 ority to conducting research on the development of
11 tests that are suitable for inspections of food at
12 ports of entry into the United States. In providing
13 for research under paragraph (1), the Secretary
14 shall under the preceding sentence give priority to
15 conducting research on the development of tests for
16 detecting the presence in food of the pathogens E.
17 coli, salmonella, cyclospora, cryptosporidium, hepa-
18 titis A, or listeria, the presence in or on food of pes-
19 ticide chemicals and related residues, and the pres-
20 ence in or on food of such other pathogens or sub-
21 stances as the Secretary determines to be appro-
22 priate. The Secretary shall establish the goal of de-
23 veloping, by the expiration of the 3-year period be-
24 ginning on the date of the enactment of the Im-
25 ported Food Security Act of 2007, tests under para-

graph (1) for each of the pathogens and substances receiving priority under the preceding sentence.

“(3) PERIODIC REPORTS.—The Secretary shall submit to Congress periodic reports describing the progress that has been made toward the goal referred to in paragraph (1) and describing plans for future research toward the goal. Each of the reports shall provide an estimate by the Secretary of the amount of funds needed to meet such goal, and shall provide a determination by the Secretary of whether there is a need for further research under this subsection. The first such report shall be submitted not later than March 1, 2008, and subsequent reports shall be submitted semiannually after the submission of the first report until the goal is met.

“(4) CONSULTATION.—The Secretary shall carry out the program of research under paragraph (1) in consultation with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Administrator of the Environmental Protection Agency. The Secretary shall with respect to such research coordinate the activities of the Department of Health and Human Services. The Secretary shall in addition consult with the Secretary of Agriculture (acting

1 through the Food Safety and Inspection Service of
2 the Department of Agriculture) in carrying out the
3 program.

4 “(5) AWARDS TO PRIVATE ENTITIES.—Of the
5 amounts reserved under section 801A(a)(2)(B)(ii)
6 for a fiscal year for carrying out the program of re-
7 search under paragraph (1), the Secretary shall
8 make available not less than 50 percent for making
9 awards of grants or contracts to private entities to
10 conduct such research.”.

11 **SEC. 4. CERTIFICATION OF FOOD IMPORTS.**

12 (a) IN GENERAL.—Chapter VIII of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
14 is amended by adding at the end the following:

15 **“SEC. 805. CERTIFICATION OF FOOD IMPORTS.**

16 “(a) IN GENERAL.—Not later than 2 years after the
17 date of enactment of this section, the Secretary shall es-
18 tablish a system under which a foreign government or for-
19 eign food establishment seeking to import food to the
20 United States shall submit a request for certification to
21 the Secretary.

22 “(b) CERTIFICATION STANDARD.—A foreign govern-
23 ment or foreign food establishment requesting a certifi-
24 cation to import food to the United States shall dem-
25 onstrate, in a manner determined appropriate by the Sec-

1 retary, that food produced under the supervision of a for-
2 eign government or by the foreign food establishment has
3 met standards for food safety, inspection, labeling, and
4 consumer protection that are at least equivalent to stand-
5 ards applicable to food produced in the United States.

6 “(c) CERTIFICATION APPROVAL.—

7 “(1) REQUEST BY FOREIGN GOVERNMENT.—

8 Prior to granting the certification request of a for-
9 eign government, the Secretary shall review, audit,
10 and certify the food safety program of a requesting
11 foreign government (including all statutes, regula-
12 tions, and inspection authority) as at least equiva-
13 lent to the food safety program in the United States,
14 as demonstrated by the foreign government.

15 “(2) REQUEST BY FOREIGN FOOD ESTABLISH-

16 MENT.—Prior to granting the certification request of
17 a foreign food establishment, the Secretary shall cer-
18 tify, based on an onsite inspection, the food safety
19 programs and procedures of a requesting foreign
20 firm as at least equivalent to the food safety pro-
21 grams and procedures of the United States.

22 “(d) LIMITATION.—A foreign government or foreign
23 firm approved by the Secretary to import food to the
24 United States under this section shall be certified to ex-

1 port only the approved food products to the United States
2 for a period not to exceed 5 years.

3 “(e) WITHDRAWAL OF CERTIFICATION.—The Sec-
4 retary may withdraw certification of any food from a for-
5 eign government or foreign firm—

6 “(1) if such food is linked to an outbreak of
7 human illness;

8 “(2) following an investigation by the Secretary
9 that finds that the foreign government programs
10 and procedures or foreign food establishment is no
11 longer equivalent to the food safety programs and
12 procedures in the United States; or

13 “(3) following a refusal to allow United States
14 officials to conduct such audits and investigations as
15 may be necessary to fulfill the requirements under
16 this section.

17 “(f) RENEWAL OF CERTIFICATION.—The Secretary
18 shall audit foreign governments and foreign food establish-
19 ments at least every 5 years to ensure the continued com-
20 pliance with the standards set forth in this section.

21 “(g) REQUIRED ROUTINE INSPECTION.—The Sec-
22 retary shall routinely inspect food and food animals (via
23 a physical examination) before it enters the United States
24 to ensure that it is—

25 “(1) safe;

1 “(2) labeled as required for food produced in
2 the United States; and

3 “(3) otherwise meets requirements under this
4 Act.

5 “(h) ENFORCEMENT.—The Secretary is authorized
6 to—

7 “(1) deny importation of food from any foreign
8 government that does not permit United States offi-
9 cials to enter the foreign country to conduct such
10 audits and inspections as may be necessary to fulfill
11 the requirements under this section;

12 “(2) deny importation of food from any foreign
13 government or foreign firm that does not consent to
14 an investigation by the Secretary when food from
15 that foreign country or foreign firm is linked to a
16 food-borne illness outbreak or is otherwise found to
17 be adulterated or mislabeled; and

18 “(3) promulgate rules and regulations to carry
19 out the purposes of this section, including setting
20 terms and conditions for the destruction of products
21 that fail to meet the standards of this Act.

22 “(i) DETENTION AND SEIZURE.—Any food imported
23 for consumption in the United States may be detained,
24 seized, or condemned pursuant to section 304.

1 “(j) DEFINITION.—For purposes of this section, the
2 term ‘food establishment’—

3 “(1) means a slaughterhouse, factory, ware-
4 house, or facility owned or operated by a person lo-
5 cated in any State that processes food or a facility
6 that holds, stores, or transports food or food ingredi-
7 ents; and

8 “(2) does not include a farm, restaurant, other
9 retail food establishment, nonprofit food establish-
10 ment in which food is prepared for or served directly
11 to the consumer, or fishing vessel (other than a fish-
12 ing vessel engaged in processing, as that term is de-
13 fined in section 123.3 of title 21, Code of Federal
14 Regulations).”.

15 (b) TRANSITIONAL PROGRAM.—Not later than 180
16 days after the date of enactment of this Act, the Secretary
17 of Health and Human Services shall promulgate regula-
18 tions to establish a transitional food safety import review
19 program, with minimal disruption to commerce, that shall
20 be in effect until the date of implementation of the food
21 import certification program under section 805 of the
22 Federal Food, Drug, and Cosmetic Act (as added by sub-
23 section (a)).

○